

Application Serial No.: 10/637,882

Supp. Amdt. dated August 3, 2006

Reply to Office Action of February 8, 2006

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CENTRAL FAX CENTER****AUG 03 2006****Amendments to the Claims:**

This listing of claims will replace all prior versions, and listings, of claims in the application:

**Listing of the Claims:**

Claim 1 (canceled): A valve prosthesis device suitable for implantation in body ducts, the device comprising:

a support stent, comprised of a deployable construction adapted to be initially crimped in a narrow configuration suitable for catheterization through the body duct to a target location and adapted to be deployed by exerting substantially radial forces from within by means of a deployment device to a deployed state in the target location, the support stent provided with a plurality of longitudinally rigid support beams of fixed length; and

a valve assembly comprising a flexible conduit having an inlet end and an outlet, made of pliant material attached to the support beams providing collapsible slack portions of the conduit at the outlet,

whereby when flow is allowed to pass through the valve prosthesis device from the inlet to the outlet the valve assembly is kept in an open position, whereas a reverse flow is prevented as the collapsible slack portions of the valve assembly collapse inwardly providing blockage to the reverse flow

Claim 2 (canceled): The valve device of claim 1, wherein the support stent comprises an annular frame.

Claim 3 (canceled): The valve device of claim 1, wherein said valve assembly has a tricuspid configuration.

Claim 4 (canceled): The valve device of claim 1, wherein said valve assembly is made from biocompatible material.

Claim 5 (canceled): The valve device of claim 4, wherein the valve assembly is made from pericardial tissue, or other biological tissue.

Claim 6 (canceled): The valve device of claim 1, wherein said valve assembly is made from biocompatible polymers.

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Claim 7 (canceled): The valve device of claim 6, wherein the valve assembly is made from materials selected from polyurethane and polyethylene terephthalate.

Claim 8 (canceled): The valve device of claim 7, wherein said valve assembly comprises a main body made from polyethylene terephthalate and leaflets made from polyurethane.

Claim 9 (canceled): The valve device of claim 1, wherein said support stent is made from nickel titanium.

Claim 10 (canceled): The valve device of claim 1, wherein the support beams are substantially equidistant and substantially parallel so as to provide anchorage for the valve assembly.

Claim 11 (canceled): The valve device of claim 1, wherein the support beams are provided with bores so as to allow stitching or tying of the valve assembly to the beams.

Claim 12 (canceled): The valve device of claim 1, wherein the support beams are chemically adhered to the support stent.

Claim 13 (canceled): The valve device of claim 1, wherein said valve assembly is riveted to the support beams.

Claim 14 (canceled): The valve device of claim 1, wherein said valve assembly is stitched to the support beams.

Claim 15 (canceled): The valve device of claim 1, wherein said beams are manufactured by injection using a mold, or by machining.

Claim 16 (canceled): The valve device of claim 1, wherein said valve assembly is rolled over the support stent at the inlet.

Claim 17 (canceled): The valve device of claim 1, wherein said valve device is manufactured using forging or dipping techniques.

Claim 18 (canceled): The valve device of claim 1, wherein said valve assembly leaflets are longer than needed to exactly close the outlet, thus when they are in the collapsed state substantial portions of the leaflets fall on each other creating better sealing.

Claim 19 (canceled): The valve device of claim 1, wherein said valve assembly is made from a coiled polymer, coated by a coating layer of the same polymer.

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Claim 20 (canceled): The valve device of claim 19, wherein said polymer is polyurethane.

Claim 21 (canceled): The valve device of claim 1, wherein the support stent is provided with heavy metal markers so as to enable tracking and determining the valve device position and orientation.

Claim 22 (canceled): The valve device of claim 21, wherein the heavy metal markers are selected from gold, platinum, iridium, or tantalum.

Claim 23 (canceled): The valve device of claim 1, wherein the valve assembly leaflets are provided with radio-opaque material at the outlet, so as to help tracking the valve device operation in vivo.

Claim 24 (canceled): The valve device of claim 23, wherein said radio-opaque material comprises gold thread.

Claim 25 (canceled): The valve device of claim 1, wherein the diameter of said support stent, when fully deployed is in the range of from about 19 to about 25 mm.

Claim 26 (canceled): The valve device of claim 1, wherein the diameter of said support stent may be expanded from about 4 to about 25 mm.

Claim 27 (canceled): The valve device of claim 1, wherein the support beams are provided with bores and wherein the valve assembly is attached to the support beams by means of u-shaped rigid members that are fastened to the valve assembly and that are provided with extruding portions that fit into matching bores on the support beams.

Claim 28 (canceled): The valve device of claim 1, wherein the support beams comprise rigid support beams in the form of frame construction, and the valve assembly pliant material is inserted through a gap in the frame and a fastening rod is inserted through a pocket formed between the pliant material and the frame and holds the valve in position.

Claim 29 (canceled): The valve device of claim 1, wherein the main body of the valve assembly is made from coiled wire coated with a coating material.

Claim 30 (canceled): The valve device of claim 29, wherein the coiled wire and the coating material is made from polyurethane.

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Claim 31 (canceled): The valve device of claim 1, wherein a strengthening wire is interlaced in the valve assembly at the outlet of the conduit so as to define a fault line about which the collapsible slack portion of the valve assembly may flap.

Claim 32 (canceled): The valve device of claim 31, wherein the strengthening-wire is made from nickel titanium alloy.

Claim 33 (currently amended): A valve prosthesis device suitable for implantation in body ducts, the device comprising a main conduit body having an inlet and an outlet and pliant leaflets attached at the outlet so that when a flow passes through the conduit from the inlet to the outlet the leaflets are in an open position allowing the flow to exit the outlet, and when the flow is reversed the leaflets collapse so as to block the outlet, wherein the main body is made from polyethylene terephthalate and collapsible leaflets are made ~~from~~ from polyurethane.

Claim 34 (canceled): The valve device of claim 33, wherein support beams made from polyurethane are provided on the main body and wherein the leaflets are attached to the main body at the support beams.

Claim 35 (canceled): The valve device of claim 33, wherein said support beams are chemically adhered to the main body.

Claim 36 (canceled): A valve prosthesis device suitable for implantation in body ducts, the device comprising:

support stent, comprised of a deployable construction adapted to be initially crimped in a narrow configuration suitable for catheterization through the body duct to a target location and adapted to be deployed by exerting substantially radial forces from within by means of a deployment device to a deployed state in the target location, the support stent provided with a plurality of longitudinally rigid support beams of fixed length;

valve assembly comprising a flexible conduit having an inlet end and an outlet, made of pliant material attached to the support beams providing collapsible slack portions of the conduit at the outlet;

substantially equidistant rigid support beams interlaced or attached to the slack portion of the valve assembly material, arranged longitudinally.

Claim 37 (canceled): A crimping device for crimping the valve device of claim 1, the crimping device comprising a plurality of adjustable plates that resemble a typical SLR camera

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variable restrictor, each provided with a blade, that are equally dispersed in a radial symmetry but each plate moves along a line passing off an opening in the center, all plates equidistant from that center opening.

Claim 38 (canceled): The crimping device of claim 37, wherein the multiple plates are adapted to move simultaneously by means of a lever and transmission.

Claim 39 (canceled): A valve prosthesis device suitable for implantation in body ducts, the device comprising:

an expandable support frame, the support frame provided with a plurality of longitudinally rigid support beams of fixed length; and

a valve assembly comprising a flexible conduit having an inlet end and an outlet, made of pliant material attached to the support beams providing collapsible slack portions of the conduit at the outlet,

whereby when flow is allowed to pass through the valve prosthesis device from the inlet to the outlet the valve assembly is kept in an open position, whereas a reverse flow is prevented as the collapsible slack portions of the valve assembly collapse inwardly providing blockage to the reverse flow.

Claim 40 (canceled): The prosthetic device of claim 39, wherein the expandable support frame comprises a deployable construction adapted to be initially crimped in a narrow configuration suitable for catheterization through the body duct to a target location and adapted to be deployed by exerting substantially radial forces from within by means of a deployment device to a deployed state in the target location.

Claim 41 (canceled): The prosthetic device of claim 39, wherein the support beams have a U-shaped cross section.

Claim 42 (canceled): The prosthetic device of claim 41, wherein a holder is used to secure the pliant material to the support beams.

Claim 43 (canceled): The prosthetic device of claim 39, wherein the support frame comprises three segments that form a circular assembly when assembled.

Claim 44 (canceled): The prosthetic device of claim 39, wherein the support beams point inwardly with respect to a central longitudinal axis of the device.

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Claim 45 (canceled): The prosthetic device of claim 43, wherein the support beams point outwardly with respect to a central longitudinal axis of the device.

Claim 46 (canceled): The prosthetic device of claim 39, further provided with a restricting tapered housing, for housing it in a crimped state.

Claim 47 (canceled): The prosthetic device of claim 39, wherein hooks are provided to secure the device in position after it is deployed.

Claim 48 (canceled): The prosthetic device of claim 39, wherein the support beams comprise longitudinal bars having a narrow slit used as the commissural attachment so that extensions the pliant material are tightly inserted through it.

Claim 49 (canceled): The prosthetic device of claim 48, wherein the extensions of the pliant material are wrapped about rigid bars serving as anchorage means.

Claim 50 (canceled): The prosthetic device of claim 49, wherein extensions of the pliant material are sutured to each other at the rigid bars.

Claim 51 (canceled): The prosthetic device of claim 50, wherein a bottom portion of the pliant material is attached to the inlet.

Claim 52 (canceled): The prosthetic device of claim 39, wherein the support beams are each provided with a rounded pole, forming a loop through which the pliant material is inserted.

Claim 53 (canceled): The prosthetic device of claim 39, wherein the pliant material is provided with longitudinal bars attached to the pliant material at positions assigned for attachment to the support frame, in order to prevent localized stress from forming.

Claim 54 (canceled): The prosthetic device of claim 39, further provided with longitudinal bars having protrusions that are inserted in bores in the pliant material, a sheet of PET and through bores provided on the support beams.

Claim 55 (canceled): The prosthetic device of claim 39, wherein the pliant material is sutured leaving the slack portions free of sutures.

Claim 56 (canceled): The prosthetic device of claim 39, wherein a connecting member with a split portion is used to connect leaflets of the pliant material to the support beams, the split connecting member compressing the pliant material in position.

Claim 57 (canceled): The prosthetic device of claim 56, wherein a portion of the connecting member is perpendicular to the split portion.

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Claim 58 (canceled): The prosthetic device of claim 39, wherein the support frame is provided with metallic members coupled to the stent and rigid members are positioned on two opposite sides of the metallic member and held against each other, holding portion of the pliant material between them, sutured, the metallic members wrapped with PET.

Claim 59 (canceled): The prosthetic device of claim 39, wherein the device is further provided with spring in order to reduce wear of the pliant material.

Claim 60 (canceled): The prosthetic device of claim 59, wherein the spring is provided with a spiral.

Claim 61 (canceled): The prosthetic device of claim 59, wherein the spring is made from stainless steel.

Claim 62 (canceled): The prosthetic device of claim 59, wherein the spring is attached to slots provided on the support frame.

Claim 63 (canceled): The prosthetic device of claim 39, wherein the pliant material is sutured to the support frame forming pockets.

Claim 64 (canceled): The prosthetic device of claim 63, wherein attachment bars are provided on the stent support at a portion of the stent close to the outlet, on which the pliant material is coupled to, and wherein the pliant material is attached circumferentially to the inlet, leaving slack pliant material.

Claim 65 (canceled): The prosthetic device of claim 39, wherein the outlet is tapered with respect to the inlet.

Claim 66 (canceled): The prosthetic device of claim 65, wherein the support frame at the outlet is wider in diameter than the pliant material forming the outlet.

Claim 67 (canceled): The prosthetic device of claim 39, wherein the pliant material is reinforced using PET.

Claim 68 (canceled): The prosthetic device of claim 39, wherein the support frame is a tube having an inner wall, having sinusoidal fold lines, wherein the pliant material is sutured to the inner wall of the tube along suture lines.

Claim 69 (canceled): The prosthetic device of claim 68, wherein additional piece of PET is added below the suture lines.

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Claim 70 (canceled): The prosthetic device of claim 39, wherein the device is incorporated with an angioplasty balloon.

Claim 71 (canceled): The prosthetic device of claim 70, wherein the balloon has a central longitudinal axis that runs along a flow path through the device, and a perimeter, the balloon comprising four inflatable portions, one portion located along a central axis and the other three located on the perimeter, the pliant material in the form of leaflets is distributed about the perimeter.

Claim 72 (New): A valve prosthesis device suitable for implantation in body ducts, the device comprising:

an annular support stent having a crimped configuration suitable for delivery through a body duct and an expanded configuration adapted for engagement with tissue at a target location, the support stent having a substantially circular profile in the expanded configuration, the support stent including an expandable frame and a plurality of longitudinally rigid support beams of fixed length; and

a valve assembly made of pliant material and having an inlet and an outlet, the valve assembly being anchored at least in part to the support beams,

whereby, when flow is allowed to pass through the valve prosthesis device from the inlet to the outlet, the valve assembly is kept in an open position, whereas a reverse flow is prevented as the collapsible slack portions of the valve assembly collapse inwardly providing blockage to the reverse flow.

Claim 73 (New): The device of claim 72, wherein the support beams are provided with bores for allowing stitching or tying the valve assembly to the support beams.

Claim 74 (New): The device of claim 73, wherein the bores extend substantially the entire length of the support beams.

Claim 75 (New): The device of claim 72, wherein the support stent includes three support beams and the valve assembly has a tricuspid configuration.

Claim 76 (New): The device of claim 72, wherein the valve assembly is made from bioprosthetic material.

Claim 77 (New): The device of claim 76, wherein the support stent is made from nickel titanium.



Claim 78 (New): The device of claim 72, further comprising at least one radiopaque marker on the support stent.

Claim 79 (New): The device of claim 78, wherein the at least one radiopaque marker on the support stent is made of a heavy metal material.

Claim 80 (New): The device of claim 72, wherein the support stent further includes a radially collapsible web between adjacent support beams, and wherein the valve assembly is anchored to both the support beams and web.

Claim 81 (New): The device of claim 72, wherein the valve assembly comprises separate leaflets and further including longitudinal bars separate from the support stent around which ends of each pair of adjacent leaflets roll and attach at the commissures.

Claim 82 (New): The device of claim 72, further including a fabric layer interposed between the valve assembly and support stent and to which both are stitched.

Claim 83 (New): A valve prosthesis device suitable for implantation in body ducts, the device comprising:

a support stent adapted to be initially crimped in a narrow configuration suitable for delivery through a body duct to a target location and adapted to be deployed to a larger diameter deployed state at the target location, the support stent being substantially tubular in its deployed state with a plurality of longitudinally rigid support beams of fixed length distributed around a circumference thereof and extending substantially co-extensively with the support stent; and

a valve assembly made of pliant material and having an inlet and an outlet, the valve assembly including a plurality of commissures each of which attaches to a support beam for providing collapsible slack portions at the outlet;

whereby, when flow is allowed to pass through the valve prosthesis device from the inlet to the outlet, the valve assembly is kept in an open position, whereas a reverse flow is prevented as the collapsible slack portions of the valve assembly collapse inwardly providing blockage to the reverse flow.

Claim 84 (New): The device of claim 83, wherein the support stent has an inlet end and an outlet end and wherein the support beams terminate at the outlet end of the support stent.

Claim 85 (New): The device of claim 83, wherein the support beams are provided with bores for allowing stitching or tying the valve assembly to the support beams.

Claim 86 (New): The device of claim 85, wherein the bores extend substantially the entire length of the support beams.

Claim 87 (New): The device of claim 83, wherein the valve assembly is stitched to the support beams.

Claim 88 (New): The device of claim 83, wherein the support stent includes three support beams and the valve assembly has a tricuspid configuration.

Claim 89 (New): The device of claim 83, wherein the valve assembly is made from bioprosthetic material.

Claim 90 (New): The device of claim 89, wherein the support stent is made from nickel titanium.

Claim 91 (New): The device of claim 83, further comprising at least one radiopaque marker on the support stent.

Claim 92 (New): The device of claim 91, wherein the at least one radiopaque marker on the support stent is made of a heavy metal material.

Claim 93 (New): The device of claim 83, wherein the support stent further includes a radially collapsible web between adjacent support beams, and wherein the valve assembly is anchored to both the support beams and web.

Claim 94 (New): The device of claim 83, wherein the valve assembly comprises separate leaflets and further including longitudinal bars separate from the support stent around which ends of each pair of adjacent leaflets roll and attach at the commissures.

Claim 95 (New): The device of claim 83, further including a fabric layer interposed between the valve assembly and support stent and to which both are stitched.

Claim 96 (New): A valve prosthesis device suitable for implantation in body ducts, the device comprising:

an outer support stent adapted to be initially crimped in a narrow configuration suitable for delivery through a body duct to a target location and adapted to be deployed to a larger diameter deployed state at the target location, the support stent being substantially tubular in its deployed state;

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an inner valve assembly made of pliant material and having an inlet and an outlet, wherein spaced commissure portions of the valve assembly are attached longitudinally to the support stent so as to provide therebetween collapsible slack portions at the outlet; and

a fabric layer interposed between the valve assembly and support stent and to which both are stitched,

whereby, when flow is allowed to pass through the valve prosthesis device from the inlet to the outlet, the valve assembly is kept in an open position, whereas a reverse flow is prevented as the collapsible slack portions of the valve assembly collapse inwardly providing blockage to the reverse flow.

Claim 97 (New): The device of claim 96, wherein the support stent has a plurality of longitudinally rigid support beams of fixed length to which the valve assembly commissures attach.

Claim 98 (New): The device of claim 96, wherein the support beams each has a series of bores formed therein, and wherein valve assembly is stitched to the bores of the support beams.

Claim 99 (New): The device of claim 98, wherein the bores extend substantially the entire length of the support beams.

Claim 100 (New): The device of claim 96, wherein the valve assembly has a tricuspid configuration with three commissures.

Claim 101 (New): The device of claim 96, wherein the valve assembly is made from bioprosthetic material.

Claim 102 (New): The device of claim 101, wherein the support stent is made from nickel titanium.

Claim 103 (New): The device of claim 96, further comprising at least one radiopaque marker on the support stent.

Claim 104 (New): The device of claim 103, wherein the at least one radiopaque marker on the support stent is made of a heavy metal material.

Claim 105 (New): The device of claim 96, wherein the support stent has a plurality of longitudinally rigid support beams of fixed length and a radially collapsible web between

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adjacent support beams, and wherein the valve assembly is anchored to both the support beams and web.

Claim 106 (New): The device of claim 96, wherein the valve assembly comprises separate leaflets and further including longitudinal bars separate from the support stent around which ends of each pair of adjacent leaflets roll and attach at the commissures.

Claim 107 (New): The device of claim 96, wherein a portion of the fabric layer forms a cuff that is wrapped around the support stent at an inlet thereof.